Missouri Statewide Health Information Exchange

Legal/Policy Workgroup

Jefferson City, MO February 9, 2010 2:30 PM – 5:00 PM





Agenda

Topic	Facilitator(s)	Time
Welcome	Co-Chairs	2:30 – 2:35 pm
Review HHS Privacy & Security Framework Principles	Co-Chairs & Manatt	2:35 pm – 2:45 pm
Key Learnings from Consent Webinar & Path Forward	Manatt	2:45 pm – 4:15 pm
Strategic Plan Update	Co-Chairs & Manatt	4:15 – 4:25 pm
Review Proposed Workgroup Work Plan	Co-Chairs & Manatt	4:25 – 4:50 pm
Next Steps	Co-Chairs & Manatt	4:50 – 5:00 pm



HHS Privacy and Security Framework Principles 12

- > **Openness and Transparency** There should be openness and transparency about policies, procedures, and technologies that directly affect individuals and/or their individually identifiable health information.
- Individual Choice Individuals should be provided a reasonable opportunity and capability to make informed decisions about the collection, use, and disclosure of their individually identifiable health information.
- Collection, Use and Disclosure Limitation Individually identifiable health information should be collected, used, and/or disclosed only to the extent necessary to accomplish a specified purpose(s) and never to discriminate inappropriately.
- Individual Access Individuals should be provided with a simple and timely means to access and obtain their individually identifiable health information in a readable form and format.
- Correction- Individuals should be provided with a timely means to dispute the accuracy or integrity of their individually identifiable health information, and to have erroneous information corrected or to have a dispute documented if their requests are denied.

Others

- ¹ In creating the HHS Privacy and Security Framework Principles, ONC relied on the Markle Foundation's core principles for a networked environment, among other available privacy and security principles. See "The Architecture for Privacy in a Networked Environment." Markle Connecting for Health Common Framework.
- ² "Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information. U.S. Department of Health and Human Services, December 15, 2008.



State Consent Policy Webinar in Review



Matt Duffy & Chris Henkenius Bass & Associates, Inc.

Deb Bass, Interim Executive Director Nebraska Health Information Initiative



Steve Larose, VP for External Affairs VT Info Technology Leaders, Inc.

Anne Cramer, Esq.
Primmer Piper Eggleston & Cramer
PC



Micky Tripathi, President Massachusetts eHealth Collaborative

Key Policies Reviewed

- Consent Model
 - Opt-in vs. opt-out and granularity details
- Available information /treatment of sensitive health information
- Permissible uses of health information
- Break-the-glass (emergency access)
- Minor consent



NeHII, VHIE & MAeHC Background

Issues like architectural model, statewide applicability of policies, policy development process, enforcement, and whether state law was amended to support HIE provide key context for evaluating consent policy decisions.

NeHII

- Hybrid federated model (Axolotl)
- NeHII is the SDE.
- Policies have statewide reach.
- Policies developed by NeHII Privacy & Security Committee (Committee of the Board).
- Compliance enforced through contracts.
- No amendment to state law (as of yet).

VHIE

- Hybrid federated model (GE Centricity)
- Exclusive statewide HIE.
- Policies have statewide reach.
- Policies developed by VITL staff & consultants with input of stakeholders; approved by Board.
- Compliance enforced through contracts.
- No amendment to state law.

MAeHC

- Each of the 3 MAeHC pilots operated a centralized repository model (eCW/Wellogic)
- Policies only applied to 3 pilots. Pilot project has concluded.
- Policies developed by pilots with input from statewide privacy workgroup (HISPC). Approved by MAeHC.
- Compliance enforced through contracts.
- No amendment to state law.



Consent Model

<u>Key Takeaway</u>: NeHII, VHIE and MAeHC each employ distinct consent models that take into account their technical architectures, state laws, and consumer/provider preferences.

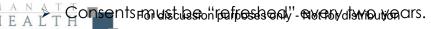
VHIE

- > Opt-in.
- > If patient signs opt-in form, data sharing is enabled between all participating treating providers (patients may not control which providers disclose their information).
- No further permission needed by participating treating providers to access data.
- Patients receive reminder every 5 years that they have right to withdraw consent.

MAeHC

- > Opt-in.
- > 94% opt-in rate.
- Patients must grant each provider consent to disclose his/her information to the HIE's clinical repository on an entity-byentity basis.
 - One pilot allowed a RHIO-wide consent to disclose.
- Unless a patient has opted-in, the patient will not show up in the HIE system at all.
- No further permission needed by participating treating providers to access data.

- Opt-out.
- > 1.5% 2.0% opt-out rate.
- Opt-out is global (all of a patient's information is excluded).
- If a patient has opted-out, the RLS will return the patient's name & demographic info with a note indicating the patient has opted-out of the exchange.
- Patients may opt back in under a process that is more strict.



Available Information/Treatment of Sensitive Health Information

<u>Key Takeaway</u>: Neither NeHII, VHIE nor MAeHC grants patients the ability to withhold certain types of health information from exchange; NeHII excludes certain sensitive health information completely.

VHIE

- Included: Eventually all PHI as defined under HIPAA, including mental health and substance abuse information.
- Excluded: None. No data filtering for sensitive health information.
- Consents for exchange of information protected under 42 CFR Part 2 (alcohol/substance abuse) carry expiration dates.

MAeHC

- Included: "Shared Health Summary," which featured: medication list, problem list, diagnosis, immunizations, allergies, smoking status, vital signs, procedures, lab results, & radiology results. Sensitive health information was included.
- Excluded: None. No data filtering for sensitive health information.
- Certain sensitive information (HIV and genetic test results) required a patient's consent each time it was made available. When pilot HIE systems identified ICD-9 and CPT codes for HIV and genetic test results, they prompted providers to obtain additional consent.
 The prompted providers to obtain additional consent.
 The prompted providers workflow complications.

- Included: Lab & x-rays, medication & immunization history, transcribed diagnostic & treatment records, allergies & drug interactions, & other transcribed clinical reports created after NeHII's start date.
- Excluded: Records related to alcohol & substance abuse treatment programs, emergency protective custody proceedings, genetic testing, HIV testing, and mental health treatment.
 - NeHII indicated during webinar that patients with sensitive health information are automatically opted-out of the exchange.

Permissible Uses of Health Information

<u>Key Takeaway</u>: VHIE, NeHII and MAeHC all allow use of health information for some variation of treatment, payment and/or health care operations. VHIE allows additional uses with explicit consent. MAeHC included use for quality improvement.

VHIE

- Treatment, payment, health care operations.
- Specific patient authorization required for "secondary uses," defined as those other than TPO, including marketing, uses by employers, and health plan use in quality review, among others.
- Clinical researchers can apply for use of de-identified data for research.

MAeHC

- Treatment, payment, health care operations and quality improvement.
- No payer use of/access to data.
- MAeHC operated a quality warehouse to aggregate and analyze data for provider performance reports, which it sent to health care providers to help improve care.

- > Treatment and payment.
 - NeHII indicated during webinar that "payment" is limited to eligibility verification by payors.
- Actively considering use of information to facilitate public health reporting.



Break the Glass (Emergency Access)

<u>Key Takeaway</u>: While VHIE, NeHII and MAeHC all noted the value in providing emergency access, none offer the service to participants.

VHIE

- ➤ N/A.
- If a patient has not opted-in, no information will be available for viewing in an emergency.

MAeHC

- ► N/A.
- All participating providers can access available information about a patient once the patient grants the disclosing provider consent to disclose.

- > Currently not permitted.
- While information about patients who opt-out is available, it is not accessible to providers.
- NeHII's Privacy & Security Committee is considering whether to allow emergency access in the future.



Minor Consent

Key Takeaway: VHIE, NeHII and MAeHC are at different stages in addressing consent for information about services to which a minor consented on his or her own.

VHIE

> No policy on minors at this time.

MAeHC

Records for minors between select ages were excluded from exchange.

NeHII

Information about STD testing or treatment of minors consented to by the minor is excluded from exchange.



Legal/Policy Workgroup Consensus Recommendations to Date

- Some form of consent should be required to exchange information through MO's statewide HIE network.
 - Model TBD (e.g. opt-in, opt-out, etc.)
 - Workgroup to engage local counsel to advise on state law requirements.
- > Type of consent required may vary depending on use of information:
 - Sharing information for treatment and quality improvement should be first order priority.
 - Public health reporting should be enabled to the extent mandated under current law.
 - Different consent may be required for other uses.
 - Marketing
 - Use by payers
 - Others TBD
- Regarding sensitive health information, there is a need to address heightened patient privacy concerns while facilitating the availability of necessary information at the point of care.
 - Workgroup to engage local counsel to advise on state law requirements.
 - Workgroup to coordinate with Consumer Engagement Workgroup.



Immediate Consent Policy Development Next Steps

Policy Decisions

- Taking into consideration the types of health information that will be available through MO's statewide HIE and state law requirements for disclosure of health information, should an opt-in or opt-out model be employed?
- How much flexibility should consumers have in permitting the sharing of their health records by entities that hold their health records? Should patients be able to control:
 - Whether and which providers may make their health records available through the exchange?
 - What types of health records providers make available through the exchange?
 - Whether and which providers may access health records through the exchange?
 - What types of health records providers may access through the exchange?

<u>Legal Considerations (Local Counsel to Advise)</u>

- Which MO laws may influence these decisions (e.g. require selection of opt-in or opt-out and/or otherwise impact granularity questions)?
 - Is there a MO law that would prohibit the inclusion of sensitive health information in the HIE or require heightened consent for such information?
 - Others?



Immediate Consent Policy Development Next Steps

Policy Decisions

- What uses of health information accessed through the HIE should be permitted?
- How long should consents last?

- How should records about services to which a minor consented on his/her own be handled?
- Should emergency access (break the glass) be permitted?

<u>Legal Considerations (Local Counsel to Advise)</u>

- Does Missouri law limit disclosures of health information for specific purposes (e.g. treatment)?
- Does Missouri law place any time restrictions on consent for disclosure of health information (if consent is required)?
- Does MO law allow minors to consent for certain types of treatment on their own and/or does MO law address disclosure of information about such treatment?
- What provisions of MO law are relevant to this issue?



Proposed Legal/Policy Workgroup Work Plan

TIMELINE	ACTIVITY	LEADERSHIP RESPONSIBILITY
Feb 23, 2010 Workgroup Mtg	Consent Model Development	
	Work through specific consent issues with assistance from local counsel: → Evaluation of potential consent model → Evaluation of points of consent (disclosure/access) → Evaluation of potential uses of information → Evaluation of types of information to be included → Evaluation of strategies for obtaining consent → Others	Co-Chairs Manatt Local Counsel
Feb 25, 2010 Advisory Board Mtg	Final Strategic Plan to Advisory Board for Review	
Feb 28, 2010	Submit Final Strategic Plan to ONC	
March 9, 2010 Workgroup Mtg	Consent Model Development Cont'd	
	Address other consent issues with assistance from local counsel: → Emergency access → Minor consent → Others TBD Finalize key decisions in advance of drafting written policies	Co-Chairs Manatt Local Counsel
March 23, 2010 Workgroup Mtg	ch 23, 2010 Workgroup Mtg 4As Webinar Presentations by technical experts → Review 4As-related CCHIT standards → Authentication 101	
March 30, 2010	Submit Draft Consent Policies to Workgroup	
April 6, 2010 Workgroup Mtg	Consent Model Finalization	
	Review draft consent policies	Co-Chairs Manatt Local Counsel
April 15, 2010 Advisory Board Mtg	Draft Operational Plan to Advisory Board	

Proposed Legal/Policy Workgroup Work Plan

TIMELINE		LEADERSHIP RESPONSIBILITY	
April 20, 2010 Workgroup Mtg	Baseline 4As/ Breach & Oversight/Enforcement Policy Development		
	Discuss adoption of statewide 4As policies → Review key decision points & progress of Technology Workgroup → Agree to process for policy development/adoption Discuss adoption of statewide breach & oversight/enforcement policies → Review key decision points & progress of Governance Workgroup → Agree to process for policy development/adoption Discuss strategy for addressing interstate HIE → Review past activity & key decision points → Agree to process for policy development/adoption/engagement with other states	Co-Chairs Manatt Local Counsel Governance Workgroup representatives	
May 4, 2010 Workgroup Mtg	Baseline 4As/ Breach & Oversight/Enforcement Policy Development		
	Review updated Operational Plan incorporating initial consensus decisions and processes related to 4As, breach & oversight/enforcement & interstate HIE	Co-Chairs Manatt Local Counsel	
May 18, 2010 Workgroup Mtg	Finalization of Materials		
	Review and finalize Operational Plan for submission to Advisory Board	Co-Chairs Manatt Local Counsel	
May 20, 2010 Advisory Board Meeting	Submit final Operational Plan to Advisory Board		
May 31, 2010	Submit Operational Plan to ONC		



Strategic Plan Status Update

- MO-HITECH Advisory Board reviewed and discussed draft HIE Strategic Plan
 - Consumer access to personal health information
 - Minor consent
 - Treatment of sensitive health information
 - Legal issues with border states
- Strategic Plan will be iterated based on Workgroup, Advisory Board, and stakeholder feedback through the end of February
 - The Strategic Plan sets out an approach to address unresolved issues/questions through the Operational Planning process
 - Strategic Plan will be updated as appropriate to incorporate decisions from Operational Planning process (after February 28th)



General Next Steps

- Review updated Strategic Plan http://dss.mo.gov/hie/action/index.shtml
 - Send feedback to <u>kwallis@manatt.com</u>

Next Meeting: Tuesday, February 23rd 2:30 – 5:00 pm Jefferson City, MO

Work through specific consent issues with assistance from local counsel:

- → Evaluation of potential consent model
- → Evaluation of points of consent (disclosure/access)
- → Evaluation of potential uses of information
- → Evaluation of types of information to be included
- → Evaluation of strategies for obtaining consent
- → Others



Appendix



Comparative Analysis of Select State Consent Policies

	Policies Apply Statewide?	Health Records Available through HIE?	Utilizes Model Statewide Form?	How Were Policies Developed & How Are They Enforced?
VT	Yes. VT operates a statewide HIE called the VT Health Information Exchange ("VHIE") operated by VT Info Tech Leaders ("VITL"). It is the only HIE in the state.	All PHI as defined under HIPAA is eligible to be included. Currently exchange a standard CCD document	Yes. VITL provides patient consent and withdrawal forms to physician practices and other HIE participants.	 Policies developed by VITL staff and board members. Participants must comply as a condition of participation in VHIE.
RI	> Yes. RI operates a statewide HIE called "currentcare." It is the only HIE in the state.	currentcare currently includes lab and pharmacy data. Intent is for all information for which exchange standards exist to be available through the HIE.	Yes.Currentcare provides form.	Codified in state law (RI HIE Act of 2008). Participants must also comply with policies as a condition of participation in currentcare.
MA	No. Policies applied only to the 3 MAeHC pilot HIEs, which did not cover the entire state. The MAeHC pilot program has concluded. There are other HIEs in the state to which these policies did not apply.	 "Shared Health Summary," which included: medication list, problem list, diagnosis, immunizations, allergies, smoking status, vital signs, procedures, lab results, & radiology results. Sensitive health information was included. 	> No.	 Policies developed and agreed to by the pilots through a collaborative process. Pilots agreed to comply with them as a condition of receiving grant funding under the MAeHC pilot program.
NY	Yes. Policies apply to all HIEs participating in the Statewide Health Information Network of NY ("SHIN- NY") and receiving state grant funds under the HEAL-NY program.	 Depends on the HIE. Statewide policies do not proscribe any restrictions on the types of records that may be exchanged. Policies suggest that HIEs assess the legal risks of making records of federally assisted alcohol and substance abuse treatment centers (42 CFR Part 2) available through the exchange. 	 Yes. Changes require approval of the Department of Health. 	 Policies developed by stakeholders through a consensus-driven process. HIEs must comply with policies as a condition of receiving grant funding under the HEAL-NY program.
MN	Yes. There are currently two operational HIEs in MN. The consent policy described here applies to/serves as a baseline for both.	 The state statute governing HIE defines health records as any information that relates to the past, present, or future physical or mental health or condition of a patient. HIEs are free to determine what records to include/exclude from exchange. 	> No.	Codified in state law (MN Health Records Act) HIEs must comply with state law when developing their own consent policies.
ME	> Yes. ME operates a statewide HIE called "HealthInfoNet." It is the only HIE in the state.	 Labs, imaging reports, prescriptions, allergies, discharge summaries, operative and consultant reports, problem lists, office visit notes. Information from substance abuse treatment facilities (42 CFR Part 2) and mental health providers as well as HIV test results and psychotherapy notes are excluded. 	 Yes. HealthInfoNet posts optout form on website. Providers may also provide forms to patients at provider sites. 	State law governing consent for disclosure of health records was amended to explicitly allow disclosure to a HIE for specified purposes without consent as long as patients could opt-out. Participants must comply with policies as a condition of participation in HealthInfoNet.
M A N A	Yes. NE operates a statewide HIE called "NeHII." There is, however, another HIE in the state that is not subject to NEHII's policies. For discussion purpo	Lab & x-rays, medication & immunization history, transcribed diagnostic & treatment records, allergies & drug interactions, & other transcribed clinical reports created after NeHIII's start date. Records related to alcohol & substance abuse treatment programs, emergency protective custody proceedings, genetic testing, HIV testing, and mental health treatment ses only a condition.	NeHII maintains opt-out form on website. Forms may be provided by and returned to participant sites.	Policies were developed by NeHII's Privacy & Security Workgroup (a committee of the NeHII Board). Participants must comply with policies as a condition of participation in NeHII.

Comparative Analysis of Select State Consent Policies

	Opt-in or Opt- out?	Can Patients Control Whether & Which Providers May Make Records Available through the Exchange?	Can Patients Control What Types of Records Providers Make Available through the Exchange?	Can Patients Control Whether and Which Providers May Access Records through the Exchange?	Can Patients Control What Types of Records Providers May Access through the Exchange
VT	In	Yes. Patient consent is required to enable data sharing between providers. Once opt-in given, any treating participating provider may make records available through the HIE.	No. All of a provider's records that fall within the scope of the information included in the exchange are made available.	Yes. Patient consent is required to enable data sharing between providers. Once opt-in given, any treating participating provider may access records available through the HIE.	> No.
RI	In	 Yes. Patient consent is required before providers may make records available. By enrolling in currentcare, patients grant consent to all of their treating participating providers (at once) to make their information available. 	No. All of a provider's records that fall within the scope of the information included in the exchange are made available.	 Yes. Patient consent is required before providers may access available records. Patients may grant this consent on a provider by provider basis. Patients may also grant consent to all treating providers only in an emergency. 	> No.
MA	In	 Yes. Patient consent was required before providers could make records available. Patients were able to grant this consent on a provider by provider basis. 	 All of a provider's records that fell within the scope of the information included in the exchange (the "Shared Health Summary") were made available. However, certain sensitive information (HIV and genetic test results) required a patient's consent each time it was made available. 	 No. All treating participating providers could access available records. 	> No.
NY	In	> No.	> No.	 Yes. Patient consent is required before providers may access available records. Patients may grant this consent on a provider by provider basis. 	> No.
MN	Hybrid	 No. If a patient's identifying information is included in a RLS, the patient can't control which providers may make their records available through the exchange. Patients may, however, opt-out of having their identifying information in a RLS, thereby opting out of the exchange entirely. 	 Not required by the statute Different HIEs free to set policies at their discretion. 	 Yes. Patient consent is required before providers may access available records (and before they may search for a patient in a RLS). Patients may grant this consent on a provider by provider basis. 	 Not required by the state statute. Different HIEs free to set policies at their discretion.
ME	Out	≻ No.	≻ No.	> No.	> No.
NE	Out	> No.	≻ No.	> No.	> No.
A N E A I OLUT	T H	For discussion purposes only	- Not for distribution		20

Comparative Analysis of Select State Consent Policies

	What Uses Are Permitted by Consent? If Additional Uses, What are the Attendant Requirements?	Duration/Revocation	How is consent to make available and/or access records about services to which a minor consented on his/her own obtained?	Is Emergency Access (Break the Glass) Permitted?
VT	 TPO as defined under HIPAA. "Quality Review" by health plans, insurers or other 3rd party payers with specific patient authorization. De-identified data may be used for research, QI and public health. 	 Until revoked (if no expiration date). Consents for providers to release records covered by 42 CFR Part 2 must have an expiration date. Patients receive reminder every 5 years that they have right to withdraw consent. 	> Under consideration.	> N/A.
RI	 Coordination of care and public health (broadly defined in statute) 	> Until revoked.	 Records for minors are made available and accessed based on parents' consent. 	> Yes.
MA	 TPO Quality improvement, and business operations. 	Two years. Consents can be revoked at will.	 Records for minors between select ages were excluded from exchange. 	> N/A.
NY	 Level1: Treatment, quality improvement, care management, and insurance coverage reviews. Level 2: Any uses of PHI other than Level 1 uses, including but not limited to payment, research and marketing. 	Consent for Level 1 uses: until revoked. Consent for Level 2 uses: must be time-limited & expire no more than 2 years after execution unless a longer duration is required to complete a research protocol.	 Records for minors age 10 & over are excluded from exchange. 	> Yes.
MN	 Not addressed by the statute. Different HIEs free to set policies at their discretion. 	Consent to access clinical information: 1 year unless a lesser period is specified in the consent or otherwise required by law. Consent to make patient identifying information available to RLS: No expiration	 Not addressed by the statute. Different HIEs free to set policies at their discretion. 	Yes. Providers may access a RLS and available clinical records without consent in an emergency. If a patient has opted-out of the RLS, however, there will be no records available to view in an emergency.
ME	> Treatment.	> N/A	Records for minors are included in the exchange unless the minor or his/her parent opts-out.	N/A. If a patient has opted-out of the exchange, there will be no records available to view in an emergency.
NE	> Treatment and payment.	> N/A	Information about STD testing or treatment of minors consented to by the minor is excluded from exchange.	No by choice. Information about patients who opt-out is available but not accessible.

